Reconsideration of the above-identified case is respectfully requested in view of the following remarks.

Claims 1-35 are pending in the Application.

I. 35 USC 112 - Rejections

The Office Action rejected Claims 4, 7, 8, 11, 14, 15, 16, 28, 30, and 32 under 35 USC 112 for being indefinite for failing to point particularly and to claim distinctly the subject matter. The dependent claims were rejected because they depend on themselves. The error was a clerical one. The noted claims have been amended to reflect the correct dependency. Applicant believes these amendments are supported throughout the Specification as filed and no new matter has been added. Reconsideration of the noted claims is respectfully requested. The Marked-Up Claims are located in Attachment A.

II. Terminal Disclaimer

The Office Action rejected Claims 1-35 as being unpatentable over Holt US Patent Number 6,348,501 B1 in view of Scivoletto US Patent Number 6,248,763 B1 under the judicially created doctrine of obviousness-type double patenting. Applicant is the owner of the Holt reference. A terminal disclaimer has been inserted to overcome the rejection in this Office Action. The terminal disclosure is located in Attachment B.

The Office Action also rejected Claims 1-32, 34, and 35 as being unpatentable over Barr US Patent Number 6,197,823 B1 in view of Holt US Patent Number 5,856,361 under the judicially created doctrine of obviousness-type double patenting. Applicant is the owner of the Barr reference. A terminal disclaimer has been inserted to overcome the rejection in this Office Action. The terminal disclosure is located in Attachment B.

Reconsideration of this application with the amended claim is respectfully requested.

Applicant duly appreciates the Examiner's time and attention to this matter.

2/S/83

Respectfully submitted,

Wendy K. Buskop Patent Attorney Reg. No. 32,202

Please mail correspondence to:

Wendy K. Buskop Buskop Law Group, P.C. 1717 St. James Place, Suite 500 Houston, Texas 77056 713.403.7411

Enclosures – Attachment A – Marked-Up Specification Attachment B – Terminal Disclaimers

ATTACHMENT A



MARKED-UP CLAIMS

CLAIMS

What is claimed is:

1. A composition comprising:

a carrier;

a capsaicin;

an encapsulation agent;

esters of amino acid; and

a light scattering element having a particle size up to 100 nm and.

an oil based alcohol.

- 2. The composition of claim 1, wherein the oil based alcohol is selected from the group, benzyl alcohol, butylene glycol, propylene glycol alcohol benzoate, benzene methanol and a hydroxy toluene.
- 3. A composition comprising:

a carrier;

a capsaicin;

an encapsulation agent;

esters of amino acid; and

a light scattering element having a particle size up to 100 nm and.

An emulsifying agent.

- 4. (Amended) The composition of claim [4] 3, wherein the emulsifying agent is selected from the group comprising: polysorbitol, sorbitol, glycerine, and corn syrup.
- 5. The composition of claim 1, wherein the carrier is selected from the group comprising: aqueous carriers, oil based carriers, fat based carriers, and fatty alcohol based carriers, corn oil, edible oil, white oil, liquid petrolatum or combinations thereof.
- 6. The composition of claim 1, further comprising at least one histidine.
- 7. (Amended) The composition of claim [7] 6, wherein the at least one histidine is a histamine hydrochloride.
- 8. (Amended) The composition as in claim [8] 7, wherein said histamine hydrochloride is a dihydrochloride.
- 9. The composition as in claim 7, wherein said histidine is selected from the group comprising: L-histidines, histamine dihydrocholoride, DL-histidine, D-histidine hydrochloride monohydrate, L-histidine hydrochloride monohydrate, L-histidine methyl ester dihydrochloride, L-histidinol dihydrochloride and combinations thereof.
- 10. The composition of claim 7, wherein said histidine has a weight percent between about 0.001\% up to about 1.0\%.
- 11. (Amended) The composition of claim [11] 10, wherein said histidine has a weight percent between about 0.025% up to 0.10%
- 12. The composition of claim 1, wherein said capsaicin is selected from the group: nordihydrocapasaicin, capsaicin, dihydrocapsaicin, homocapsaicin, and combinations thereof.
- 13. The composition as in claim 1 wherein said capsaicin is in the range of 0.0001% to 62% by weight of capsaicin.

- 14. (Amended) The composition of claim [14] 13, wherein said capsaicin is in the range of 0.025 to 20 wt. %.
- 15. (Amended) The composition of claim [15] 14, wherein said capsaicin is in the range of 0.025 to 2 wt. %.

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- 16. (Amended) The composition as in claim [16] 15, wherein said capsaicin is in the range of 0.025% to 0.25% by weight.
- 17. The composition as in claim 1 wherein said encapsulation agent is selected from the group comprising: colloidal oatmeal, hydrogenated lecithin, and dipotassium glycyrrhizinate and combinations thereof.
- 18. The composition of claim 1, wherein said esters of amino acids are selected from the group: menthyl and lauryl esters of amino acids and combinations thereof.
- 19. The composition as in claim 1, wherein said esters of amino acid are between 0.10 wt. % and 1.0 wt. %.
- 20. The composition as in claim 1, wherein said esters of amino acid are menthyl adequate to achieve 0.1 to 16 wt. % menthol in the formulation.
- 21. The composition of claim 19 wherein said ester is menthyl lauryl pidolate.
- 22. The composition of claim 1, wherein said light scattering element has a particle size of up to 100 microns in diameter.
- 23. The composition of claim 20, wherein said light scattering element has a particle size of between about 30 microns and about 60 microns in diameter.
- 24. The composition of claim 1, wherein said light scattering element is selected from the group: titanium dioxide, zinc oxide, and benzophenones, methoxy cinnamate, para amino benzoic acid, octyl dodecyl neopentanoate, aluminum stearate with titanium dioxide, aluminum oxide with titanium dioxide, and combinations thereof.

- 25. The composition of claim 1, further comprises an additional anti-itch agent which is a member of the group: methyl sulphonyl methane, sodium bicarbonate, calamine, allantoin, kaolin, cortisone, anti-inflammatory steroids, anti-allergic steroids and derivatives or combinations thereof.
- 26. A patch for treating arthritis and neurological pains consisting of an elastomeric adhesive unit on which is disposed a formulation comprising:

a carrier;

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a capsaicin;

an encapsulation agent:

a histidine, and

an ester of amino acid.

Polysorbitol

27. A gel comprising:

a carrier;

a capsaicin;

an encapsulation agent:

an ester of amino acid; and

a light scattering element having a particle size up to 100 nm.

Benzyl alcohol

- 28. (Amended) The gel of claim [28] <u>27</u>, further comprising a histidine.
- 29. A sunscreen comprising.

a carrier; a capsaicin; an encapsulation agent: an ester of amino acid; and a light scattering element having a particle size up to 100 nm. Benzoyl alcohol (Amended) The sunscreen of claim [30] 29, further comprising histidine. A cream for treating pruritis comprising: a carrier; a capsaicin; an encapsulation agent: an ester of amino acid; and a light scattering element having a particle size up to 100 nm. Benzyl alcohol (Amended) The cream of claim [32] 31, further comprising histidine and polysorbitol. A transdermal application comrprising: a carrier

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30.

31.

32.

33.

a capsaicin

an encapsulating agent

an ester of amino acid,

a light scattering element having a particle size up to 100 nm

niacin,

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histimine dicholoride

polsorbitol

- 34. The composition of claim 1, further comprising aloe.
- 35. The composition of claim 3, further compirisng aloe.